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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,589	02/12/2001	Luis Rafael Herrera Estrella	408.0003	5829
7590	03/09/2005		EXAMINER	
William J. Bundren 734 Larue Road Millersville, MD 21108			LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/701,589	HERRERA ESTRELLA, LUIS RAFAEL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 14 December 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,17,27,32,37,47,57 and 67 is/are pending in the application.
- 4a) Of the above claim(s) 47 and 57 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,17,27,32,37 and 67 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of species (3) (the 35S promoter of the cauliflower mosaic virus, claim 67) filed on November 10, 2004 and the response to the notice of non-compliant amendment filed on December 14, 2004 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 1, 17, 27, 32, 37, and 67 will be examined.

### ***Specification***

2. The disclosure is objected to because of the following informalities: there is no description for Figure 7 in Brief Description of the Drawings.

Appropriate correction is required.

### ***Claim Objections***

3. Claim 1 is objected to because of the following informality: no period should appear after the label of each step, e.g., "a." should be --a--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 27, 32, 37, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Gallardo *et al.*, (Planta, 197, 324-332, 1995).

Gallardo *et al.*, teach that monocotyledonous C4 NADP(+-)malate dehydrogenase I efficiently synthesized, targeted to chloroplasts and processed to an active form in transgenic plants of the C3 dicotyledon tobacco.

Regarding claim 1, since Gallardo *et al.*, teach to construct a vector having a chimeric gene comprising 355 promoter of the cauliflower mosaic virus, cDNA of chloroplastic NADP(+-)malate dehydrogenase and nopaline synthetase polyadenylation region, and transform the constructed vector into *Nicotiana tabacum L.* via *Agrobacterium tumefaciens* to create a transgenic tobacco (see page 324, abstract, page 325, left and right column and Figure 1, page 326, right column, last paragraph, and page 327, left column), Gallardo *et al.*, disclose preparation of a recombinant heterologous DNA molecule encoding one or more genes for enzymes that synthesize organic acids (ie., cDNA of chloroplastic NADP(+-)malate dehydrogenase), linked to a promoter sequence functional in plants (ie., 355 promoter of the cauliflower mosaic virus), and to a transcription termination/polyadenylation sequence functional in plants (ie., nopaline synthetase polyadenylation region), wherein the recombinant DNA molecule comprises a gene that codes for an enzyme selected from the group consisting of citrate synthase, a gene of *Pseudomonas aeruginosa* that codes for citrate synthase, and malate dehydrogenase and the transformation of plant cells with the recombinant DNA molecule (ie., a vector having a chimeric gene comprising 355 promoter of the cauliflower mosaic virus, cDNA

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of chloroplastic NADP(+) - malate dehydrogenase and nopaline synthetase polyadenylation region) as recited in steps a) and b) of claim 1. Since Gallardo *et al.*, teach to replicate *Nicotiana tabacum* to regenerate transgenic plants from the transformed cells or the seeds of the transgenic plants (see page 326, right column, last paragraph, and page 327, left column), Gallardo *et al.*, disclose the regeneration of transgenic plants starting from transformed cells, or of seeds from plants obtained from these transformed cells, for one or several generations, wherein the genetic information of these transformed cells includes the recombinant DNA molecule coding for enzymes that synthesize organic acids as recited in step c) of claim 1.

Regarding claim 27, Gallardo *et al.*, teach that the promoter is a constitutive promoter (see page 327, left column, last paragraph).

Regarding claims 32 and 37, Gallardo *et al.*, teach that the promoter is a root-specific promoter (see page 329, right column, last paragraph).

Regarding claim 67, Gallardo *et al.*, teach that the promoter is the 355 promoter of the cauliflower mosaic virus (see page 324, abstract).

Therefore, Gallardo *et al.*, teach all limitations recited in claims 1, 27, 32, 37, and 67.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gallardo *et al.*, (1995) as applied to claims 1, 27, 32, 37, and 67 above, and further in view of Christou *et al.*, (US Patent No. 5,015,580, published on May 14, 1991).

The teachings of Gallardo *et al.*, have been summarized previously, *supra*.

Gallardo *et al.*, do not disclose that the transcription termination sequence is the transcription termination sequence of the nopaline Synthetase gene as recited in claim 17.

Christou *et al.*, teach that a vector containing a chimeric gene for suitable for expression in plants generally must include, besides the coding sequence of the desired exogenous or foreign gene, appropriate flanking regulatory sequences such as a suitable promoter capable of promoting transcription and expression *in vivo* in plant cells, a transcription terminator capable of signalling the end of transcription, and a translation terminator suitable to terminate translation of messenger if protein synthesis is desired. A suitable termination sequence effective in plants is the polyadenylation sequence from the nopaline synthase gene of *Agrobacterium tumefaciens* (see column 11, second paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the methods recited in claim 17 wherein the transcription termination sequence is the transcription termination sequence of the nopaline synthetase gene in view of prior art of Gallardo *et al.*, and Christou *et al.*. One having ordinary skill in the art would have been motivated to do so because Christou *et al.*, suggest that a suitable termination sequence effective in plants that contains in a vector containing a chimeric gene is the polyadenylation sequence from the nopaline synthase gene (see column 11, second paragraph). One having ordinary skill in the art at the time the invention was made would have

been a reasonable expectation of success to use the transcription termination sequence of the nopaline synthetase gene as the transcription termination sequence in a recombinant heterologous DNA molecule recited in claim 17 because constructing a recombinant heterologous DNA molecule recited in claim 17 by cloning a fragment containing both the transcription termination sequence and the polyadenylation sequence from the nopaline synthase gene would save time and cost for one having ordinary skill in the art since the transcription termination sequence and the polyadenylation sequence of the nopaline synthase gene are adjacent each other and a restriction fragment containing the transcription termination sequence and the polyadenylation sequence from the nopaline synthase gene is easy to obtain.

### ***Double Patenting***

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claim 37 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 32. When two claims in an application are duplicates, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu  
PSA  
March 4, 2005

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

3/7/05